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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/459,141	06/02/1995	PHILLIP W. BERMAN	P0233C6	3929

22798 7590 12/16/2002

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EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 12/16/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/459,141

Applicant(s)

BERMAN ET AL.

Examiner

Ulrike Winkler, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 September 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-23 and 25-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-23 and 25-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 49.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1648

DETAILED ACTION

The Amendment filed September 23, 2002 (Paper No. 48) in response to the Office Action of March 15, 2002 is acknowledged and has been entered. 1 Claims 10-23 and 25-41 are pending and are currently being examined.

A copy of the interview summary from the October 24, 2002 interview with applicant's representative Emily Haliday is attached to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Specification

The objection to the specification as failing to provide proper antecedent basis for the claimed subject matter is **withdrawn** in view of applicant's arguments.

The objection to the specification as failing to provide proper antecedent basis for the claimed subject regarding the term "immunogenic composition" is **withdrawn** in view of applicant's arguments.

Claim Rejections - 35 USC § 112

The rejection of claims 10, 32, 40 and 41 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for producing neutralizing antibodies in mice when they are injected with truncated HSB gD glycoprotein, does not reasonably provide enablement for using any truncated glycoprotein as an immunogen to elicit neutralizing antibodies from any

Art Unit: 1648

virus, fungal, microbial or parasitic organism that would be effective at protecting the animal from challenge by the pathogen is **withdrawn** in view of applicant's arguments. In the interview October 24, 2002 with applicant's representative Emily Haliday, it was suggested that applicant possibly amend the claim into a Jepson claim format for clarification. The claim should indicate that the invention encompasses taking a known composition that has proven efficacy and deleting the transmembrane domain from the polypeptide. This would clarify the claims, as it would exclude any composition that has not been shown to have efficacy.

Double Patenting

The double patenting rejection of claims 10-12, 14-19, 25-29, 32-41 under the judicially created doctrine of double patenting over claims 13, 19 and 20 of U. S. Patent No. 4,855,224 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent is **maintained** for reasons of record.

Applicant's arguments have been fully considered, the arguments suggest that a double patenting rejection may only consider the claims. This is not found persuasive as MPEP 804 provides that the specification can be consulted when making an obvious type double patenting rejection.

MPEP 804: When considering whether the invention defined in a claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art. This does not mean that one is precluded from all use of the patent disclosure. The specification can always be used as a dictionary to learn the meaning of a term in the patent claim. *In re Boylan*, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent. *In re Vogel*, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in *Vogel* recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention

Art Unit: 1648

claimed in an application is an obvious variation of an embodiment disclosed in the patent which provides support for the patent claim. According to the court, one must first “determine how much of the patent disclosure pertains to the invention claimed in the patent” because only “[t]his portion of the specification supports the patent claims and may be considered.” The court pointed out that “this use of the disclosure is not in contravention of the cases forbidding its use as prior art, nor is it applying the patent as a reference under 35 U.S.C. 103, since only the disclosure of the invention claimed in the patent may be examined.”

In the instant rejection, the structure of the prior patent is the same as that in the present invention, adding descriptive phrase “capable of raising neutralizing antibodies *in vivo*” has not altered the structure of the composition. Because antibodies recognize structure, the prior patent structure is the same as the present structure and therefore meets the limitation of “capable of raising neutralizing antibodies *in vivo*”. Therefore, the double patenting rejection is **maintained**.

Please note that there was no restriction requirement in any of the priority documents, applicant originally filed two separate patent applications one directed to the diagnostic composition and the other directed to the vaccine composition.

Claims 10-23 and 25-41 are rejected under the judicially created doctrine of double patenting over claims 13, 19 and 20 of U. S. Patent No. 4,855,224 in view of Watson et al (Science 1992) and Dundarov et al. (Dev Biol Stand. 1982) in view of Watson et al (Science 1992) and Dundarov et al. (Dev Biol Stand. 1982) is **maintained** for reasons of record.

Applicant’s arguments have been fully considered (see above). However, the structure of the prior patent is the same as that in the present invention, adding descriptive phrase “capable of raising neutralizing antibodies *in vivo*” has not altered the structure of the composition. Because antibodies recognize structure, the prior patent structure is the same as the present structure and

Art Unit: 1648

therefore meets the limitation of "capable of raising neutralizing antibodies *in vivo*". Therefore, the double patenting rejection is **maintained**.

The double patenting rejection of claims 10, 11, 14-19 and 32-41 are rejected under the judicially created doctrine of double patenting over claims 1-10 of U. S. Patent No. 5,851,533 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent ~~is maintained~~^{mm} for reasons of record is **withdrawn** because a Terminal disclaimer has been filed as Paper No. 20 in the instant application.

Claims 10-23 and 25-41 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over 1-5, 9, 13, 21, 22 and 25-27 of U. S. Patent No. 5,851,533 in view of Watson et al (Science 1992) and Dundarov et al. (Dev Biol Stand. 1982) is **withdrawn** because a Terminal disclaimer has been filed as Paper No. 20 in the instant application.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1648

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ulrike Winkler, Ph.D.


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1800-1600